Conflicts of Interest on US and Australian Government Vaccine Advisory Boards (Krimsky 2003)

Representatives on government vaccine advisory boards in both the USA and Australia have many conflicts of interest (COI) with industry and are still allowed to participate in policy-decisions made by these boards. The government regulators for medicines/vaccines in these countries (US Food and Drug Administration (FDA) and the Australian Therapeutic Goods Administration (TGA)) are 100% funded by the industries whose drugs they license for public use and monitor for safety in the population. This is called a User-Pay or Cost-Recovery System. The decision making boards in these organisations are dominated by industry representatives.

An investigation in 1999 – 2000 of the Federal US vaccine policy advisory committees revealed the endemic nature of COI within these bodies (Committee on Government Reform in Krimsky 2003). The investigation revealed that within these policy-making committees the COI rules were weak and rarely enforced. Members with significant COI were given waivers to participate in committee proceedings. It was found that the 2 main advisory boards developing government policy on vaccines – the ACIP and the VRBPAC – were dominated by representatives with close financial ties to vaccine producers. The investigation found that both the CDC and FDA allow members to vote on vaccine recommendations even when they have significant financial ties to drug companies and can make large profits from the decisions that are made.

An Example of the COI's

An example of the endemic nature of COI is provided with the approval process for Rotavirus vaccine in 1998. In critical discussions regarding the approval of the new rotavirus vaccine, members of the ACIP who had COI were granted waivers for the entire year –

regardless of the nature of the COI. Out of the 8 members of the CDC's ACIP committee, who supported the vaccine's inclusion on the childhood schedule, 4 had direct financial interests with the vaccine manufacturers. On the FDA's VRBPAC committee there were 5 full-time FDA committee members who voted for the approval of the vaccine and 3 of these had financial ties to either Wyeth Lederle (the manufacturer of the vaccine) or the other companies who were developing competitor vaccines.

A summary of the nature of conflicts of interest on the US Food and Drug Administration (FDA) boards and the Centre for Disease's Control and Prevention (CDC) vaccine advisory boards include (Krimsky 2003 p.95 - 100):

- Members of the FDA and CDC advisory committees who make policy decisions own stock in drug companies that make vaccines.
- Representatives on both advisory committees can own patents for vaccines that are under consideration for licensure or for recommendation on the national schedule of vaccines.
- The CDC grants conflict of interest waivers to every member of their advisory committee a year at a time and allows full participation in the discussions leading up to a vote by every member, whether they have a financial stake in the decision or not.
- In the early 2000's the CDC's advisory committee had no public members – no community member's, whose only interest is health, has a vote on whether a vaccine belongs on the childhood immunization schedule or not.
- The FDA's committee in 2000 had only one public member and this individual received travel expenses and honoraria from Merck.
- The FDA is also 100% funded by the companies whose products the agency approves and monitosr for safety – a User-Pay system.

Some examples of the substantial ties members of the ACIP had to pharmaceutical companies when the rotovirus vaccine was being considered included a member with 600 shares in Merck worth $33,800 and another member, Paul Offit, who shared the patent on a competitor rotavirus vaccine in development by Merck at the time.

Paul Offit is Chief of the Division of Infectious Diseases and Director of the Vaccine Education Centre at the Children's Hospital of Philadelphia (CHOP). He has been a consultant for Merck for many years and this pharmaceutical company finances his research chair ($1.5million) at the Philadelphia hospital. He also received a grant from Merck for $350,000 to work on a rotovirus vaccine against gastroenteritis. This hospital is affiliated with the Medical School at the University of Pennsylvania.

As a co-inventor of a rotavirus vaccine for which he was a patent holder, Offit was due to make millions of dollars from a decision to support the approval of the first vaccine made by Wyeth Lederle in 1998. The rotavirus vaccine was approved by the industry dominated committees in 1998, but it led to many children being harmed and was withdrawn from the market in the same year. This led to an investigation in 1999 into the policy-decisions made by the CDC and FDA which was conducted by the US Government Reform Committee (Attkinson 2008).

In 2006 when Merck's rotavirus vaccine – RotaTeq – was approved by the FDA, Paul Offit received patent rights with his co-inventors Fred Clark and Stanley Plotkin (Olmsted and Blaxill 2011). This entitles them to receive ongoing royalties from the Children's Hospital of Philadelphia (CHOP) and the Wistar Institute to whom they ceded their inventor rights (Olmsted and Blaxill 2011). These institutes have collaborated in developing this vaccine since the 80's. When the vaccine was approved by the FDA for the US National Immunisation Program (NIP), Offit received millions of dollars in royalties. Yet he had been allowed to participate in the decision-making process for its approval in 1998 while his

vaccine was protected by patent and undergoing clinical trials with Merck. When CHOP sold its royalty interest in RotaTeq in 2007 it was worth $182 million (Olmsted and Blaxill 2011). Paul Offit is clearly not a disinterested 'expert' and yet he is the face of the US government's advocacy for the safety of vaccines and the debunking of the link between vaccines and autism.

In 1999 the US government reform committee investigation found that there were no standards for COI within the FDA and CDC expert advisory committees. Even if a member owned up to $100,000 in stock or was being paid $250,000 a year by the affected company the conflict would be waived. This situation was known in 1992 when the Institute of Medicine called for changes but the recommendations were not acted upon.

This indicates that COI have been normalised in these agencies in the process of approving vaccines/drugs. In fact, a new law was added to the ethical guidelines in 1997 that allows the FDA to add official industry representatives to advisory committees. As the COI rules are not enforced in the CDC and FDA, it is clear that policy decisions are not being made by representatives who are non-biased. Board members are making value judgments (opinions) on the welfare of the public which also bring large financial rewards to themselves. This situation can be described as self-serving, nepotism, abuse of power, self-dealing or insider-trading and is a breach of the trust the public has in government regulators (Krimsky 2003).

Reference:

Krimsky S, 2003, Science in the Private Interest: has the lure of profits corrupted biomedical research? Rowman and Littlefield Publishers Inc, USA.